

510(k) Summary
AS1000
Arobella Medical, LLC

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

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Date: April 1, 2009

807.92(a)(2)

Trade Name: AS1000 Ultrasonic Wound Therapy System
Common Name: Ultrasonic Wound Therapy System
Classification Name(s): Wound Cleaner,
Ultrasound
Classification Number: NRB

807.92(a)(3)

Predicate Device(s)

| | | |
|-----------------------|--|---------|
| Celleration | Celleration Mist Therapy System | K050129 |
| Arobella Medical, LLC | AR1000 Ultrasonic Wound Therapy System | K062544 |
| DeRoyal | Jetox-ND | Class I |
| Smith & Nephew | VersaJet Hydrosurgery System | K060782 |

807.92(a)(4)

Device Description

The AS1000 Ultrasonic Wound Therapy System promotes wound healing through the ultrasonic lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue) and cleansing irrigation & maintenance debridement of the site for the removal of debris, exudates, fragments, bacteria, and other matter through the use of low-frequency, low-intensity, non-thermal non-contact ultrasonic energy and oxygenated fluid irrigation.

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This is accomplished by the non-contact, non-thermal application of a fine oxygenated fluid stream spray to the wound bed whereby ultrasound energy is transmitted via the stream from the applicator tip to the wound tissue. Non-contact ultrasound provides cellular stimulation, increased blood flow, and reduced bioburden with much less pain or thermal-effect than competing direct contact ultrasound devices. The AS1000 uses continuous ultrasonic energy to oxygenate the fluid (typically sterile saline) into a solution stream and couple the delivery of ultrasonic energy via the stream to the treatment site.

The level of airborne ultrasound energy generated by the device, its spatial characteristics, and the potential exposure to unwanted acoustic energy is substantially equivalent between the AS1000 device and the predicate Celleration MIST device since both have the same size diameter (10mm) oscillating surface generating the ultrasonic energy transmitted thru their respective streams. In addition, since both the AS1000 device and the predicate Celleration MIST device are intended to treat tissue at the same distance and same pattern, the level of ultrasound energy transmitted to the patient and the effects of the distance of the applicator from the wound is substantially equivalent. As the AS1000 device and the predicates (Celleration MIST device and Arobella AR1000 device) are all derived from classic Langevin transducer designs, the variability in the field from device to device is expected to be substantially equivalent, and all AS1000 devices are tested and verified to perform within the reported parameters to maintain safety and efficacy

The converter has a transducer horn that is made from titanium alloy (TI-6AL-4V). The applicator and tip are made from titanium alloy (TI-6AL-4V), like the probes for Celleration MIST and Arobella AR1000 predicated devices, and the other indirect patient-contact materials are stainless steel (both AISI Type 300 & 17-4PH series), anodized aluminum alloy (6061), nylon, polyurethane, and silicone tubing. No latex is used in this device, including any potential patient-contact areas, and testing has revealed no negative reactions to the materials used in this device.

Specifications:

| | |
|------------------------|--|
| Generator Power Source | 115VAC, 2.5A, 50/60Hz |
| Converter Power Output | <140 watts |
| Amplitude | 0um ~ 80um |
| Frequency | 35kHz (± 3 kHz) |
| Weight | Generator: ~16.5 lbs Handheld Applicator: ~1.5lbs |
| Approximate Dimensions | System 18" D x 14" W x 8" H |

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Storage Temperature -20 to 50° C at a maximum relative humidity of
90% (non-condensing)

Operating Temperature 0 to 40° at a maximum relative humidity of 90%
(non-condensing)

807.92(a)(5)

Intended Use(s)

Promotes wound healing through lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue) and maintenance debridement for the removal of debris, exudates, fragments, bacteria and other matter.

807.92(a)(6)

Technological Characteristics
(see tables on following pages)

| COMPARISON TABLE | | Arobella Medical AS1000 Ultrasonic Wound Therapy System | Cellation (www.cellation.com) Mist Therapy System | DeRoyal (TAVTECH Ltd.) (www.deroval.com; alt www.tav-tech.com) JetOx-ND System | Arobella Medical (www.arobella.com) ARI 000 (Quasie) Wound Therapy System | Smith & Nephew (wound.smith-nephew.com/usHome.asp) VersaJet Hydrosurgery System |
|---|--|--|--|--|--|--|
| Indications For Use | | Promotes wound healing through lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue) and maintenance debridement for the removal of debris, exudates, fragments, bacteria, and other matter. | Promotes wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria | Cleansing and debridement of wounds such as pressure ulcers, diabetic and venous ulcers, burns, traumatic wounds, difficult-to-heal tissue, and postsurgical wounds. | Selective dissection & fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and cleansing irrigation of the site for the removal of debris, exudates, fragments, and other matter. | Wound debridement, soft tissue debridement, and cleansing of surgical site and burns |
| 510(k) or PMA Submission / CFR Citation | | Pending Submission | K032378 / K050129 | Exempt (880.5475 Jet Lavage) | K062544 | K991383 / K011612 / K060782 |
| Primary Device Agent | | Low-Intensity Low-Frequency Ultrasound (35kHz) | Low-Intensity Low-Frequency Ultrasound (40kHz) | Focused Irrigant Stream Mixed With Oxygen | High-Intensity Low-Frequency Ultrasound (35kHz) | Pressurized Fluid Stream & Evacuation |
| Agent Delivery | | Oxygenated Irrigant (e.g. Saline) & Non-Contact Probe | Atomized Saline Irrigant & Non-Contact Probe | Atomized Oxygenated Saline Irrigant | Saline Irrigation & Contact Probe | Saline Irrigation Jet / Station Nozzle |
| Agent Mechanism | | Ultrasound lavage spray for cleansing irrigation of wound bed over course of treatment | Ultrasound wound cleansing and maintenance debridement | Wound lavage cleansing and debridement | Ultrasound for selective tissue dissection and fragmentation and irrigation of wound bed over course of treatment | Pressurized stream and evacuation cuts, ablates, and removes tissue and foreign matter and surgically removes/removes material |
| Treatment Variable | | Applicator shape/positioning, frequency and duration of treatments; irrigant flow rate | Applicator positioning, frequency and duration of treatments; Mist flow rate | Applicator positioning, frequency and duration of treatments; irrigant flow rate | Applicator size/positioning/contact surface, frequency and duration of treatments; irrigation flow rate | Applicator positioning, frequency and duration of treatments; flow and evacuation rate |
| Treatment Setting | | Hospital, clinic, in-home, or intraoperative settings | Hospital, clinic, or in-home settings | Hospital, clinic, or in-home settings | Hospital, clinic, in-home, or intraoperative settings | Hospital, clinic, or intraoperative settings |
| Pre Use Sterilization | | Probe - Autoclave or Steam Sterilize; Shield - Single-Use Packaged Disposable | Probe - Cleaned/Disinfected; Applicator - Sterile Single-Use Packaged Disposable | Applicator - Sterile Single-Use Packaged Disposable | Probe - Autoclave or Steam Sterilize; Shroud - Sterile Single-Use Packaged Disposable | Probe/Pump - Sterile Single-Use Packaged Disposable |
| Material(s) in Patient Contact | | Probe (Horn & Tip) - Ti-6Al-4V | Probe - Ti-6Al-4V Applicator - Polymer Resin | Tubing - Elastomer Resin Applicator - Polymer Resin | Probe (Horn & Tip) - Ti-6Al-4V | Probe - AISI Type 300? Disposable Pump Housing - Polymer Resin |
| Post Use Disposition | | Probe - Reusable, Single Patient Use Post-Sterilization, User-Sterilizable; Shield - Disposable, Single Patient Use | Probe(s) - Reusable, User-Cleanable; Applicator - Disposable, Single Patient Use | Applicator & Tubing - Disposable, Single Patient Use | Probe - Reusable, Single Patient Use Post-Sterilization, User-Sterilizable | Probe/Pump - Disposable, Single Patient Use Only |

| | Arobella Medical AS1000 Ultrasonic Wound Therapy System | Cellation (www.cellation.com) Mist Therapy System | DeRoyal (TAVTECH Ltd.) (www.deroval.com; alt www.tav-tech.com) JetOx- ND System | Arobella Medical AR1000 Ultrasonic Wound Therapy System | Smith & Nephew (woundsmith-nephew.com) us/home.asp VersaJet HydroSurgery System |
|-------------------------|---|--|--|---|--|
| Ultrasound Intensity | Variable 10%-100% (0.1 - 0.5 W/cm ²) | Preset based on wound size (0.1 - 0.5 W/cm ²) | No ultrasound effect | Variable 10%-100% (0.1 - 2.0 W/cm ²) | No ultrasound effect |
| Operational Modes | Continuous or pulsed ultrasound | Continuous ultrasound | Continuous flowstream | Continuous or pulsed ultrasound | Continuous flowstream |
| Coupling Interface | Sterile oxygenated-fluid (saline) stream | Sterile saline mist | Sterile oxygenated-fluid (saline) stream | Sterile saline stream | Sterile saline stream |
| Aerosolization | Minimal | Minimal | Minimal | Minimal | Minimal |
| Fluid Splatter | Yes | Yes | Yes | Minimal | Yes |
| User Controls | Foot Pedal & Panel Buttons (Oxygen & Fluid Valving) | Button & Fluid Valving On Applicator Body | Oxygen & Fluid Valving | Foot Pedal & Panel Buttons (Fluid Valving) | Panel Buttons (Fluid Valving) |
| Treatment Time | Varies on wound size (1-5 minutes) | Varies on wound size (3-20 cm) | Varies on wound size (3-10 minutes) | 1-5 minutes | 1-5 minutes |
| Treatment Distance | 5-15 mm | 5-15 mm | 10-25 mm | Contact with applicator probe | Contact with cutting stream |
| Treatment Pattern | Mesh (Top-Bottom, Left-Right) | Mesh (Top-Bottom, Left-Right) | Mesh (Top-Bottom, Left-Right) | Depends on tissue selected for removal | Depends on tissue selected for removal |
| Debridement | Maintenance | Maintenance | Maintenance | Selective / Volumetric Ablation | Precision cutting |

807.92(b)

Safety and Effectiveness

The AS1000 Ultrasound Wound Therapy System is substantially equivalent to the Celleration MIST system and the Arobella AR1000 Ultrasonic Wound Therapy System as well as the DeRoyal JetOx ND and Smith+Nephew VersaJet.

1.0 Efficacy

This device, like the predicates, is directed for single (1) treatment, and total recommended treatments shall be no more than three (3) times per week or as directed on the order of the physician; typical treatment regimen is approximately two (2) weeks or more, depending on the size and nature/condition of the treated area as well as other subject dependent factors, but may be prescribed for more frequent use and/or for a shorter or longer treatment regimen duration on the order of a physician.

This device also compares with the predicates, as follows:

1. Controlled ultrasonic delivery of oxygenated-fluid irrigation, primarily recommended for use with 0.9% sterile saline solution and filtered oxygen, to lavage the wound tissue (e.g. acute and chronic wounds, burns, diseased or necrotic tissue), like the Celleration predicate ultrasonic wound cleanser though with the addition of oxygenated-irrigant and like the DeRoyal JetOx predicate jet lavage with the additional of ultrasound.
2. Maintenance debridement of the site for the removal of loose fragments, debris, exudate, bacteria, and other matter, like the Celleration predicate ultrasonic wound cleanser though with the addition of oxygenated-irrigant and like the DeRoyal JetOx predicate jet lavage with the additional of ultrasound.
3. Ultrasonic separation/debridement of tissue through the use of the applicator and tip, either parallel to the wound bed surface for shallow separation of tissue layers, like the predicate Smith+Nephew hydrosurgical device, or normal to the wound bed for non-contact cavitation ablation of the unwanted tissue, like the Arobella AR1000 predicate selective, contact debridement device but instead with low-intensity, non-thermal, non-contact ultrasonic energy and like the low-intensity, low-frequency Celleration predicate ultrasonic wound cleanser though with the addition of oxygenated-irrigant.
4. As a result, the AS1000 promotes wound or tissue healing, like the Celleration predicate ultrasonic wound cleanser though with the addition of oxygenated-irrigant. There is significant clinical literature (see list of Example References Cited in the Technical Device Description) as precedence to support the use of therapeutic ultrasound to demonstrate the different aspects and characteristics associated with or required for the promotion of wound healing (e.g. stimulation of blood flow, fibrin promulgation, macrophage stimulation/bacteria destruction, and so forth).

In addition, the 2008 CPT codebook provides a Class III for this treatment modality as 0183T - Low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care, per day. The Instructions For Use (IFU) for more specific examples of the applicator's use, and the entire system is compact in size such that it can be used at a primary care provider's office (on an out-patient basis), clinic, specialized treatment center (i.e. burn center), or hospital, like all of the predicate devices.

2.0 Safety

The AS1000 system consists of an ultrasonic power supply (hereto after referred to as a generator), an ultrasonic converter hand piece (or just converter), an applicator & tip, a saline supply reservoir & conduit tubing, a oxygen supply reservoir & conduit tubing, and, optionally, a waste chamber for material removed by aspiration. This establishes substantial equivalence to the Celleration predicate ultrasonic wound cleanser and Arobella AR1000 predicate selective, contact debridement device. The option to aspirate establishes substantial equivalence to the Smith+Nephew VersaJet and the DeRoyal JetOx HDC (though not listed in the comparison table, the JetOx HDC is essentially the JetOx ND with the addition of aspiration).

2.1 Electrical Safety & Electromagnetic Compatibility

Like the relevant predicates, this device complies with the following standards:

- IEC 60601-1 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical electrical equipment, Part 1-2: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-4 Medical electrical equipment, Part 1-4: Programmable electrical medical systems
- FCC Part 18 - EMC Requirements

2.2 Ultrasonic Safety

Like the relevant predicates, this device complies with the following standards:

- 21 CFR 1050.10 – Ultrasonic therapy products
- IEC 61847 Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics

2.3 Biocompatibility

Like the relevant predicates, this device was tested for and complies with the standard ISO 10993-1:2003 - Biological evaluation of medical devices, Part 1: Evaluation and testing and its

relevant annexes (based on nature and duration of patient contact). All testing was conducted in compliance to 21 CFR, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies.

The AS1000 system is preferred to be used with 0.9% sterile saline solution, which is widely available for purchase from medical suppliers in bottle or bag form and is to be supplied by the user, as well as the tubing, valving (for saline flow control), and connector (for attachment to the converter). Alternately, the AS1000 can also be used with other FDA-approved irrigants. This is comparable to all of the predicate devices and irrigation solutions.

2.4 Transportation/Storage

Packaging systems for the non-sterile device and for the non-sterile accessories of the device (e.g. the applicator, tips, shroud, optional aspiration port, et al) keep the product without deterioration and without a specific level of sterility stipulated, like all the predicate devices. Those accessories used specifically for treatment (e.g. applicator, tip, shroud, etc) are to be sterilized prior to use to minimize the risk of microbial contamination, like the predicate Arobella AR1000 selective, contact debridement device. In addition, the packaging system will be subjected to the appropriate testing (as applicable) to ensure the device and the accessories arrive in usable and functioning condition for use, like the predicate devices.

As the device and the accessories are durable goods with little or no notable deterioration, the shelf life is at the very least as long as the product lifecycle, barring storage, transportation, and/or use under extremes of environmental conditions (e.g. temperature, humidity, moisture, etc).

2.5 Reprocessing

This device is virtually identical from an infection control perspective to the Arobella AR1000 wound debridement device for which we have previously validated the reprocessing instructions. The instructions for reprocessing (i.e. cleaning and sterilizing) the device from the IFU are identical to the predicate Arobella AR1000 which have already been validated.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 19 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arobella Medical, LLC
% Eliaz Babaev
5929 Baker Road, Suite 470
Minnetonka, Minnesota 55345

Re: K091038

Trade/Device Name: AS1000 Ultrasonic Wound Therapy System
Regulation Number: 21 CFR 878.4410
Regulation Name: Low energy ultrasound wound cleaner
Regulatory Class: II
Product Code: NRB, FQH
Dated: April 1, 2009
Received: April 13, 2009

Dear Eliaz Babev:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

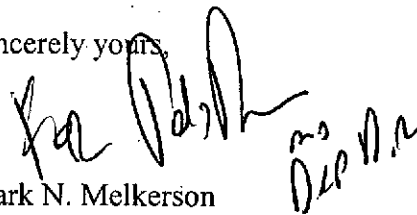
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091038

Device Name: AS1000 Ultrasonic Wound Therapy System

Indications for Use:

Promotes wound healing through lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue) and maintenance debridement for the removal of debris, exudates, fragments, bacteria and other matter.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krane for MSA
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091038